

SEP 24 2001

K012149



### **XIII. STATEMENT OF SAFETY AND EFFECTIVENESS**

#### **510(k) SUMMARY OF SAFETY AND EFFECTIVENESS POWDER-FREE LATEX EXAMINATION GLOVES WITH PROTEIN & CHEMOTHERAPY LABELING CLAIM**

**Manufacturer:** Allegiance Healthcare Sdn. Bhd.  
Plot 87 Kampung Jawa  
Bayan Lepas  
Penang, West Malaysia 11900

**Regulatory Affairs Contact:** Erica Sethi  
1500 Waukegan Road, Bldg. WM  
McGaw Park, IL 60085

**Telephone:** (847) 785-3337

**Date Summary Prepared:** June 21, 2001

**Common Name:** Patient Examination Glove

**Classification:** Glove, Examination (Latex)

**Predicate Devices:** Positive Touch Powder-Free Latex Examination Gloves With Protein and Chemotherapy Labeling Claim

**Description:** Powder Free Examination Gloves With Protein and Chemotherapy Labeling Claim are formulated using latex and are coated with a Polymer coating. These gloves are offered non-sterile in sizes X-small, Small, Medium, Large and X-large.

**Intended Use:** Powder-Free Latex Examination Gloves With Protein and Chemotherapy Labeling Claim are disposable devices intended for medical purposes that are worn on the examiner's hands or fingers to prevent contamination between patient and examiner. These gloves have been tested for use with chemotherapy drugs using ASTM F 739-99a.



### **XIII. STATEMENT OF SAFETY AND EFFECTIVENESS**

#### **510(k) SUMMARY OF SAFETY AND EFFECTIVENESS (con't) POWDER-FREE LATEX EXAMINATION GLOVES WITH PROTEIN AND CHEMOTHERAPY LABELING CLAIM**

**Substantial Equivalence** Powder Free Examination Gloves With Protein and Chemotherapy Labeling Claim are substantially equivalent to Positive Touch Powder-Free Latex Examination Gloves in that they provide the following characteristics:

- intended use
- size, design, product features
- made of natural rubber latex
- physical characteristics

#### **Summary of Test Results:**

##### **Test**

##### **Result**

**Primary Skin Irritation**

Glove does not display irritation potential.

**Guinea Pig Maximization**

Glove does not display sensitization potential.

**Ultimate Elongation  
& Tensile Strength**

Glove meets or exceeds requirements for rubber examination gloves per ASTM D3578-00.

**Barrier Defects**

Glove meets or exceeds requirements per 21 CFR §800.20 and ASTM D3578-00, AQL=2.5.

**Powder Level**

Glove meets powder level requirements for "Powder Free" designation per ASTM D 3578-00.

**Protein Labeling Claim**

Glove meets requirements for protein claim of 50 microgram or less of total water extractable protein per gram of glove using the ASTM Lowry test method (ASTM 5712-95).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP 24 2001

Ms. Erica Sethi  
Manager of Regulatory Affairs  
Allegiance Healthcare Corporation  
1500 Waukegan Road, Building WM  
McGaw Park, Illinois 60085

Re: K012149

Trade/Device Name: Powder-Free Latex Examination Gloves with Protein,  
Chemotherapy Labeling Claim

Regulation Number: 880.6250

Regulation Name: Patient Examination Gloves

Regulatory Class: I

Product Code: LYY

Dated: June 21, 2001

Received: July 10, 2001

Dear Ms. Sethi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

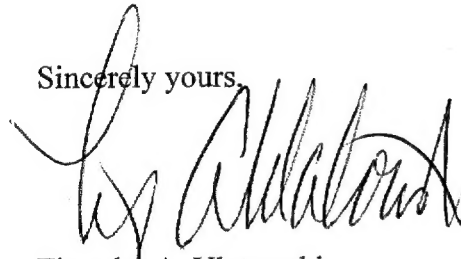
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (section 531-542 of the Act; 21); CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Timothy A. Ulatowski", written over the "Sincerely yours," text.

Timothy A. Ulatowski  
Director

Division of Dental, Infection Control  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure



**Allegiance Healthcare Corporation**  
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McGaw Park, Illinois 60085-6787  
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Applicant: Allegiance Healthcare Corporation

510(k) Number: K012149

Device Name: Powder-Free Latex Examination Gloves With Protein, Chemotherapy Labeling Claim

Indications For Use: A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. This latex glove contains 50 micrograms or less of total water extractable protein per gram. In addition, this glove has been tested for use with chemotherapy drugs.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE)

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_ or Over-The Counter Use \_\_\_\_\_  
(Per 21 CFR 801.109)

  
(Division Sign-Off)

Division of Dental, Infection Control,  
and General Hospital Devices

510(k) Number

K012149